

TESTIMONY OF RICHARD C. WENDER, M.D.
TO THE PRACTICING PHYSICIANS ADVISORY COUNCIL
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My name is Richard Wender, M.D. I am the chair of the Department of Family Medicine at Jefferson Medical College of Thomas Jefferson University in Philadelphia, where I have been a member of the faculty for the past 20 years. My clinical practice and teaching activities focus on cancer prevention and screening. I worked with the Centers for Disease Control to develop its current "Call to Action" program to promote Primary Care Physician awareness of colorectal cancer screening. I have co-authored several screening guidelines for the American Cancer Society, including the colorectal cancer screening guideline, and have worked extensively with the Cancer Research Foundation of America, and the National Colorectal Cancer Roundtable to develop ways to reach more Americans with preventive services. I am the past president of both the Philadelphia and Pennsylvania Divisions of the American Cancer Society, (ACS), and I serve as one of seven at-large members of the National Board of Directors of ACS, where I have chaired the Cancer Control Committee.

I am pleased to be able to address you on the subject of immunoassay fecal occult blood tests ("FOBTs"). The notice for this meeting included a question, which asked if immunoassay FOBTs are an appropriate substitute for guaiac fecal occult blood tests when screening for colorectal cancer. I respectfully submit that the answer is that immunoassay FOBTs are better than guaiac-based fecal occult blood tests; they should be covered under the Medicare colorectal cancer screening benefit and they should be reimbursed at a rate comparable to other cancer immunoassays.

Colorectal cancers are the second leading cause of cancer deaths in the United States; the CDC estimates that approximately 56,600 Americans will die from this disease this year.

Colorectal cancer is fundamentally a disease of aging, with incidence rates increasing significantly after age 50. Even though Medicare covers annual fecal occult blood testing using the guaiac test, the GAO reported earlier this year that only 25% of eligible Medicare beneficiaries had fecal occult blood tests in the past year. This figure is the lowest utilization rate for any preventive service studied by the GAO and signals a failure to make these tests available to Medicare patients.

Ideally, a screening test for colorectal cancers and precancerous adenomas should be highly sensitive and highly specific for bleeding in the lower gastrointestinal tract, and should encourage compliance with the test protocol. Guaiac-based tests, which are the only fecal occult blood tests currently covered under Medicare and are based on technology that is over 30 years old, suffer from several key drawbacks that can reduce test sensitivity and produce false positive results: (1) they detect heme present in the stool, which can originate from bleeding anywhere from the mouth to the anus, (2) they cannot distinguish human heme from heme present in many foods, such as dietary meats; (3) they indiscriminately detect peroxidase activity, which is present in a range of fruits and vegetables; and (4) they detect heme present in stool caused by side effects of certain medications, including non-steroidal anti-inflammatory drugs. As a result, for a guaiac test to be useful, patients must eliminate these foods and medications for several days preceding the test, and during the 3-day period during which stool samples are collected. Furthermore, guaiac tests must trade off lower specificity whenever sensitivity is increased.

Immunoassay FOBTs eliminate each of these key drawbacks, and produce a combination of sensitivity and specificity that is superior to guaiac. See Allison, JE, et al., A Comparison of

Fecal Occult Blood Tests For Colorectal Cancer, N. Engl. J. Med. 1996;334:155-9. Unlike guaiac, which detects the heme portion of hemoglobin, immunoassay FOBTs are based on the detection of human globin protein. They are specific for lower gastrointestinal bleeding, do not react with animal hemoglobin, peroxidase compounds, or with medications that can produce false positive results that can lead to unnecessary diagnostic colonoscopies. Immunassays are highly sensitive for lower g.i. bleeding, without the corresponding specificity loss that affects the accuracy of guaiac FOBTs. Moreover, the improvements inherent in the immunoassay FOBT have vastly simplified the sample collection process; unlike guaiac-based tests, the immunoassay FOBT cleared for use by the FDA does not require that a patient collect and smear feces on a card. Instead, the patient uses a brush to collect several drops of water from around the surface of the stool while it is in the toilet bowl. This distinction has been shown in clinical studies to improve compliance from approximately 25% for guaiac tests to approximately 40% for immunoassay tests. The public health benefit is unmistakable: improved compliance can lead to improved early detection of significant neoplasia, and treatment that can reduce colorectal cancer incidence and mortality among Medicare beneficiaries.

The benefits of immunoassay FOBTs have been recognized in articles published in The New England Journal of Medicine, Gastroenterology, and in presentations at conferences sponsored by the American Gastroenterological Association and other professional organizations. See Allison, JE, et al., A Comparison of Fecal Occult Blood Tests For Colorectal Cancer, N. Engl. J. Med. 1996;334:155-9; St. John, DJ, Young, GP, et al., Evaluation of New Occult Blood Tests for Detection of Colorectal Neoplasia, Gastroenterology 1993; 104:1661-68; Young, GP, Cole, SR, et al., Population Participation in Screening Improves Markedly Using an Immunochemical Fecal Occult Blood Test with Simplified Fecal Sampling, Gastroenterology

2002; Supplement for Digestive Disease Week and Annual Meeting of the American Gastroenterological Association at A-484. In addition, the benefits of immunoassay FOBTs have already been demonstrated in other countries, including Japan and Australia, where they are in widespread use.

Immunoassay FOBTs also provide an additional benefit to patients and their physicians. Unlike guaiac-based tests, which are usually developed in a physician's office and are often difficult to interpret, immunoassay tests are performed in a CLIA-certified laboratory using calibrated equipment and trained personnel. The additional resources needed for immunoassay FOBT are comparable to those required for other cancer immunoassays currently covered under Medicare. This additional level of quality control ensures that test results provide more reliable data to physicians and their patients.

A standard reference work in the field of medical decision-making states that for patients with a particular pretest probability, or clinical likelihood of disease, the test with the highest expected utility, based on the performance characteristics of the test, is the preferred testing alternative.¹ The underlying technical characteristics of immunoassay FOBTs provide a better balance of high sensitivity and high specificity than guaiac FOBTs; this translates into higher utility for physicians and patients. When the improved compliance and quality control characteristics are added to the analysis, immunoassay FOBTs are clearly better than guaiac FOBTs as a screening method for colorectal cancers and precancerous adenomas. I respectfully request that you join me in encouraging rapid recognition of screening coverage for

¹ Harold C. Sox, Jr., M.D., et al., Medical Decision Making. Butterworth-Heinemann (1988) at 280.

immunoassay FOBTs paid at an appropriate rate, comparable to other cancer immunoassays, that will support the availability of these tests for Medicare beneficiaries.